

DEPARTMENT OF HEALTH AND HUMAN SERVICES

September 26, 1995

Dr. W. Martin Strauss
Agricultural Regulation Director
Monsanto Company
Suite 1100
700 14th Street, NW
Washington, DC 20005

Dear Dr. Strauss:

This is in regard to Monsanto's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on canola line GT73 which is genetically modified to be tolerant to the herbicide glyphosate. The new canola variety has been rendered tolerant to the herbicide glyphosate by the expression of the 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) gene isolated from *Agrobacterium* sp. strain CP4 and a mutated version of the wild type glyphosate oxidoreductase (GOX) gene from *Achromobacter* sp. stain LBAA (GOXv247).

On March 6, 1995, Monsanto met with FDA to discuss their safety and nutritional assessment of canola line GT73. As part of bringing Monsanto's consultation with FDA regarding this product to closure, Monsanto submitted a summary assessment of new canola line GT73 on April 3, 1995. These communications informed FDA of the steps taken by Monsanto to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that Monsanto has concluded that this new canola variety is not materially different in composition, safety, or any other relevant parameter from canola varieties currently on the market and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF 0020 and that will be maintained in the Office of Premarket Approval.

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Based on the information Monsanto has presented, we have no additional questions concerning this product at this time. However, as you are aware, it is Monsanto's continued responsibility to ensure that foods the firm markets are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan Rulis, Ph.D.
Acting Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

cc: HFS-200 HFS-205 HFS-206 HFS-226 HFS-235 HFS-246 HFS-247
HFS-013 HFV-144 HFV-200 HFV-221 HFV-226 HFV-230 BNF 0020